

REMARKS

Claims 1 and 5-13 are currently pending. Claims 1, 5-10, and 11-12 are amended by way of the present amendment. Claims 2 and 4 is canceled without prejudice or disclaimer as to the underlying subject matter. Support for the amended and newly added claims may be found in the originally presented claims and in the Specification, for example, at page 5, lines 12-13 (Table); page 6, lines 6-7 (Table); page 8, lines 6 – page 9, line 8, page 10, line 17 – page 11, line 12; and page 11, lines 13-16.

I. Election/Restriction

Applicants note the finality of the restriction requirement and continue to respectfully disagree with the Examiner's restriction requirement. Accordingly, Applicants respectfully request that the Examiner rejoin and consider Claims 1-2 and 4-13.

Applicants note that in the Written Opinion mailed May 6, 2006 for international application PCT/FR2004/002848 from which the present application is based, the International Searching Authority determined that Claims 1-13 were properly examined together as a single invention. That is, the International Searching Authority determined that Claims 1-13 did not lack unity of invention and were so linked as to form a single general inventive concept. In evaluating National stage applications derived from PCT applications filed pursuant to 371, the USPTO is also required to evaluate the claims under the lack of unity standard. M.P.E.P. § 1850 and 37 C.F.R. § 1.475. Namely, in national stages cases where unity of invention was already determined, the USPTO is precluded from independently revisiting the inquiry and instead, the USPTO is bound by what the International Bureau has already determined. As such no restriction requirement can be made in the present application Claims 1-13 must be examined together¹.

¹ If the USPTO Examiner wants to overturn the IB's decision on unity, the Examiner must make an Agency determination that there is lack of Unity of Invention, according to the PCT, Articles, Rules (13), and Administrative Instructions including Annex B. See *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 650 F., Supp. 218, 23 USPQ 590 (ED VA 1986). Here, the Examiner simply has not made any such showing.

II. Specification

The Examiner has objected to the Specification as containing embedded hyperlinks. Office Action at page 3. In response, Applicants have amended the Specification by modifying the referenced embedded hyperlinks on pages 6-7 of the Specification. As such, withdrawal of the objection to the Specification is respectfully requested.

III. Rejection under 35 U.S.C. § 112, first paragraph, written description

Claims 1, 2, and 12 stand rejected under 35 U.S.C. § 112, first paragraph, written description “as failing to comply with the written description requirement.” Office Action at page 3. Applicants respectfully disagree with the rejection under 35 U.S.C. § 112, first paragraph, but have amended Claims 1 and 11-12 by specifying the specific deleted genes in the claimed strain. As such, the rejection of Claims 1, 2, and 12 under 35 U.S.C. § 112, first paragraph, written description is rendered moot and withdrawal of the rejection is respectfully requested.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175. Indeed, the Federal Circuit stated that “[i]t is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention.” *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005).

In rejecting the claims, the Examiner asserts that “the claims are drawn to a genus of microorganisms having one or more of its NADPH-oxidizing activities limited and wherein it has also undergone medications that favor one or more of its NADP+-reducing enzyme activities.” Office Action at page 5. The Examiner further asserts that “[s]pecifically, the claims

lack written description because it is clear that experimentation would be required to determine which alterations in any particular microorganism would have the recited function of NADH-oxidizing activities limited, and the NADP⁺-reducing enzyme activities modified to be favored.” *Id.* at page 6. Applicants disagree.

As amended, the strain of Claim 1 now specifies the deletion of at least one gene coding for a quinone oxidoreductase and/or a soluble transhydrogenase as well as the deletion of at least one gene coding for a phosphoglucose isomerase and/or a phosphofructokinase. A person of ordinary skill in the art would, after reading the present Specification, understand that Applicants were in possession of this claimed subject matter. For example, without being limited, the Specification sets forth strains containing “the deletion of a gene coding for a quinone oxidoreductase (*e.g. qor*, ZTA1) and/or a gene coding for a soluble transhydrogenase activity (*e.g. udhA*).” Specification at pages 8, lines 6-10. Moreover, the Specification further specifies “the deletion of one or several genes coding for phosphoglucose isomerase activity (*e.g. pgi*, PGI1) and/or phosphofructokinase activity (*e.g. pfkA*, PFK1).” Specification at page 8, line 12 – page 9, line 2. The Specification also sets forth Tables which include at least one gene associated with NADPH oxidizing enzyme activity as well as at least one gene associated with NADP⁺-reducing enzyme activities. Specification at pages 5-6. Accordingly, one of skill in the art would recognize that Applicants were in possession of the claimed subject matter.

The Examiner has offered no evidence to demonstrate, in light of the Applicants’ disclosure, why one of ordinary skill in the art would reasonably doubt that the invention encompassed by the claims has not been adequately described in the present disclosure. Therefore, Applicants respectfully request that the Examiner withdraw the written description rejections under 35 U.S.C. § 112, first paragraph.

III. Rejection under 35 U.S.C. § 112, second paragraph, indefiniteness

Claim 11 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Office Action at page 7. In rejecting the claims, the Examiner asserts that “the ‘optionally’ of claim 11 is vague and indefinite since it is not clear how the option of not including the activities that follow ‘optionally’ would result in the modified microorganism of claim 1.” Solely in order to facilitate prosecution, the term “optionally” has been deleted from

Claim 11 per the Examiner's suggestion. As such, the rejection under 35 U.S.C. § 112, second paragraph, is rendered moot and withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the amendments and remarks above, Applicants respectfully submit that this application is in condition for allowance and request favorable action thereon. The Examiner is invited to contact the undersigned if any additional information is required.

Applicants believe that no fees are due. If any additional fees are required, they may be charged to Deposit Account No. 50-4254, referencing Attorney Docket No. 2903925-027000.

Respectfully submitted,

BAKER, DONELSON, BEARMAN, CALDWELL
& BERKOWITZ, P.C.

/David L. Vanik/

David L. Vanik, Ph.D.
Registration No. 64,547

Susan E. Shaw McBee
Registration No. 39,294

Date: March 31, 2010

Customer No.: **84331**

555 Eleventh Street, N.W.
Sixth Floor
Washington, DC 20004

Telephone: 202-508-3400
Facsimile: 202-508-3402